



State of New Hampshire
DEPARTMENT OF ENVIRONMENTAL SERVICES

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November 13, 2003

CERTIFIED MAIL

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RETURN RECEIPT REQUESTED

NOTICE OF PAST VIOLATION

CYTYC Corporation
2 Perimeter Road East
Londonderry, New Hampshire 03053

Attn: Mr. Richard C. Walker, EH & S Coordinator

Re: CYTYC Corporation
Londonderry, New Hampshire
EPA ID # NHD500011275

Dear Mr. Walker:

On October 8, 2003, the Department of Environmental Services, Waste Management Division (DES) conducted an inspection of the CYTYC Corporation (CYTYC). The purpose of the inspection was to determine CYTYC's compliance status relative to RSA Ch. 147-A and the New Hampshire Hazardous Waste Rules, Env-Wm 100-1100.

As a result of the inspection and review of the information provided to DES, the following deficiencies were documented:

1. Env-Wm 509.02(a)(1) – General Inspection Requirements

A review of CYTYC's Hazardous Waste Inspection Checklist revealed: 1) a notation for observing deterioration due to corrosion or other factors; and 2) the date and nature of repairs or remedial actions taken, were not documented.

Env-Wm 509.02(a)(1), which references 40 CFR 265.15, requires full quantity generators to conduct and document inspections of the facility, including hazardous waste storage areas. The inspections are required to be recorded in a log which includes the area being inspected, the date and time of the inspection, the name of the inspector, a notation of the observations made, and the date and nature of the repairs or other remedial actions taken.

DES requested that CYTYC amend the existing Hazardous Waste Inspection Checklist to reflect a notation for observing deterioration due to corrosion or other factors, and the date and nature of any necessary repairs or remedial actions taken. Submit an updated Hazardous Waste Inspection Checklist to DES.

In an October 14, 2003 submittal from Mr. Richard C. Walker, E H & S Coordinator, documentation was provided demonstrating that CYTYC's Hazardous Waste Inspection Checklist was modified to include: 1) a notation for observing deterioration due to corrosion or other factors; and 2) the date and nature of any repairs or remedial actions taken. No further action is required.

2. Env-Wm 509.02(a)(2) – Personnel Training

At the time of the inspection, CYTYC's facility training records failed to document a training program which includes a list of hazardous waste job titles, job descriptions, descriptions of introductory and continuing training to be provided for each position, and names of employees filling each position.

Env-Wm 509.02(a)(2), which references 40 CFR 265.16, Personnel Training, requires full quantity generators to maintain specific documents and records related to personnel training at the facility.

DES requested that CYTYC maintain a written personnel training program which provides a list of hazardous waste job titles, job descriptions, descriptions of introductory and continuing training to be provided for each position, and names of employees filling each position. Please submit a copy of this personnel training program to DES.

In an October 14, 2003 submittal, Mr. Richard C. Walker provided a written personnel training program which provides a list of hazardous waste job titles, job descriptions, descriptions of introductory and continuing training to be provided for each position, and names of employees filling each position. No further action is required.

3. Env-Wm 509.02(a)(5) – Contingency Plan

A review of CYTYC's contingency plan revealed deficiencies regarding the following:

The emergency coordinator's home and office addresses;

Providing vital information concerning any possible hazards to human health or the environment, outside the facility, during an emergency;

Procedures for ensuring that all equipment has been cleaned and is fit for use before resumption of operations;

Instructions to notify local authorities that the facility is in compliance with 40 CFR 265.56(h)(1) & (2) before resumption of activities; and

The facility contingency plan did not list specific elements to be included in a 15 day report, listed in 40 CFR 265.56(j), that address details of the incident.

Env- Wm 509.02(a)(5), which references 40 CFR 265, Subpart D, requires full quantity generators to maintain a complete contingency plan at the site.

DES requested that CYTYC revise and update its contingency plan to correct any deficiencies as identified in the enclosed Contingency Plan Module.

In an October 14, 2003 submittal from Mr. Richard C. Walker, documentation was provided demonstrating that CYTYC's contingency plan was complete. No further action is required.

4. Env-Wm 509.02(b)– Emergency Posting

At the time of the inspection, CYTYC's emergency posting at the nearest telephone to the hazardous waste storage area was present but incomplete.

Env-Wm 509.02(b) requires that full quantity generators shall post a list of the steps to take if an emergency occurs and the following emergency numbers at the nearest telephone to the hazardous waste storage area:

- (a) The emergency coordinators (home and office);
- (b) The fire department, police department, and State of New Hampshire and local emergency response teams that may be called upon to provide emergency services, unless the facility has a 24-hour response team designated to provide emergency services whose number is posted; and
- (c) The location of fire extinguishers and spill control material, and if present, fire and internal emergency alarms.

DES requested that CYTYC post the required information at the nearest telephone to the hazardous waste storage area.

In an October 14, 2003 submittal from Mr. Richard C. Walker, documentation was provided demonstrating that CYTYC's emergency posting was complete. No further action is required.

5 Env-Wm 509.03- Satellite Storage Requirements

At the time of the inspection, one (1) 55-gallon satellite accumulation container of hazardous waste "Methanol" was observed in the Main Manufacturing Area (MMA). Inspectors later discovered that hazardous wastes generated in the Quality Lab (upstairs) were routinely added to the MMA satellite. Therefore, MMA satellite container served as a consolidation point which was not at or near the point of generation, or under the control of the process operator.

Env-Wm 509.03 requires that all satellite storage areas be located at or near any point of generation where the wastes initially accumulate and be under the control of the operator of the process generating the waste.

DES requested that CYTYC place an additional hazardous waste satellite accumulation container in a location that is at or near the point of generation. As an alternative to this strategy, CYTYC may also elect to immediately deliver hazardous waste generated in the Quality Lab to the designated hazardous waste storage area upon its generation.

In a letter received on October 14, 2003, Mr. Richard C. Walker documented CYTC's compliance with the Full Quantity Generator Satellite Storage Requirements. According to the letter, "A satellite container has been placed in the QC Laboratory Area. Laboratory QC vials are no longer transported to the Manufacturing Area satellite container." No further action is required.

The October 8, 2003 inspection revealed that a large portion of CYTYC's hazardous waste stream consists of methanol that is in unused, product form. As a result, DES inspectors recommended that CYTYC explore possible avenues for reusing the waste methanol internally, or by outside entities. Proper management and reuse of the waste methanol, in accordance with Env-Wm 803.04- "Materials that are Not Wastes When Recycled," as well as Env-Wm 803.05- "Documentation of Claims that Materials are Not Wastes and are Exempt from Regulation," may result in a substantial economic benefit to CYTYC. Furthermore, recycling efforts may enable CYTYC to lower its hazardous waste generator status to a Small Quantity Generator. The DES Pollution Prevention Program assists generators with reuse and waste elimination strategies, and is available at the phone number listed below.

DES believes the deficiencies identified during the inspection have been corrected and acknowledges receipt of a report describing the corrective measures taken by CYTYC to achieve compliance. Accordingly, no further action in response to the listed deficiencies is required. However, DES personnel may reinspect your facility at a later date to determine whether the facility is maintaining full compliance with the applicable rules. Fines may also be pursued for any or all violations observed during this or subsequent inspections of the facility.

Enclosed you will find a copy of the completed Hazardous Waste Generator Inspection Report which documents the compliance status of your facility at the time of the inspection. This checklist may also be of value to you for use in determining future compliance with the New Hampshire Hazardous Waste Rules.

The State of New Hampshire Hazardous Waste Rules, as well as much other useful information, can be obtained from DES's website at <http://www.des.state.nh.us/hwcs/>, or by contacting the Public Information Center at (603) 271-2975.

It is the goal of DES to promote the prevention of pollution at the source as the preferred option for meeting established environmental quality goals. We strive to ensure that pollution prevention options are considered first, followed by recycling, treatment and disposal. I am

requesting that the DES's Pollution Prevention Coordinator, Stephanie D'Agostino, contact you to discuss possibilities for waste minimization or source reduction at your facility. In the meantime, if you have immediate questions about pollution prevention, please feel free to contact her at 271-6398.

As a service to New Hampshire's hazardous waste generators, we maintain a Hazardous Waste Assistance Hotline which is available for you to contact our knowledgeable staff of hazardous waste inspectors. Our hazardous waste staff is available to answer your questions concerning the New Hampshire Hazardous Waste Rules and the compliance issues which affect your hazardous waste management program. The technical assistance available through the Hotline includes fact sheets that pertain to the management and recycling of specific wastes, summary sheets of specific sections of the Hazardous Waste Rules, copies of EPA and New Hampshire hazardous waste policy or regulatory interpretation letters that may benefit your operation, and networks with other state or federal agencies to answer your questions on a national level. The Hotline is available Monday through Friday, 8:00 AM to 4:00 PM toll free at (866) HAZ-WAST (in-state only) or at (603) 271-2942.

If you believe that the deficiencies documented in this NOPV have been cited in error, or if you have any questions regarding this letter, please contact the lead inspector, Eric K. Abrams or John J. Duclos, Supervisor of the Hazardous Waste Compliance Section at 271-2942. Specific questions regarding water related issues may be directed to Sharon Ducharme of DES's Water Division at 271-3307, and for air related issues, please contact Pam Monroe of DES's Air Resources Division at 271-1370. Thank you for your cooperation.

Sincerely,



Kenneth W. Marschner, Administrator
Waste Management Programs
Waste Management Division

cc: DB/RCRA/NOPV/RPB/Archives
Frederick J. McGarry, P.E., DEE, Chief Engineer, Acting Director, WMD
Gretchen Rule Esq., Administrator, DES Legal Unit

E-mail: JJD/SD/SD/PM

Enclosure: Inspection Modules